K060343

510(k) Summary

MAY 11 2006

APPLICANT NAME:	Sentech Korea Corp.
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CONTACT:	Mr. Soo Hyun Kim, Managing Director
DATE:	11/18/2005

1. Identification of Device

Proprietary/Trade Name: AL-6000 Breath Alcohol Tester
Classification Name: Device, Breath Trapping, Alcohol, DJZ
Common Name: Breath Alcohol Test System

2. Equivalent Legally Marketed Device

AlcoMate (Model CA2000) – KHN Solutions, LLC / K041334

3. Indications for Use (Intended Use)

The AL-6000 is intended to measure alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcoholic intoxication.

4. Device Description

The AL-6000 is a Breath Alcohol Tester designed to measure alcohol in the human breath. The AL-6000 meets or exceeds the requirements of the US DOT (Department of Transportation) and NHTSA (National Highway Traffic Safety Administration). The device takes a breath sample of at least three (3) seconds in order to capture an accurate "deep-lung air" sample. This sample is analyzed by a semiconductor-based gas sensor in order to calculate Breath Alcohol Concentration (BrAC), which is then converted to an equivalent Blood Alcohol Concentration (BAC).

The STK3100 semiconductor sensor consists primarily of a sensing layer and heating element, which is formed by an n-type semiconductor powder and heater, respectively. When the heater is powered in clean air,

oxygen molecules in the air trap electrons in the semiconducting material after which they are chemically absorbed on the surface of the powder particles. However, when the STK3100 is exposed to ethanol vapor, the absorbed oxygen (O^- or O_2^-) reacts with the gas and is reduced. By this reaction, the electrons trapped by the oxygen are released and flow through the semiconductor, which means that resistance decreases and electrical conductivity increases.

5. Substantial Equivalence Chart

	Device: AlcoMate CA2000	**Device: AL-6000**
Indications for Use	Measures alcohol content in the human breath for detection/diagnosis of alcoholic intoxication	Measures alcohol content in the human breath for detection/diagnosis of alcoholic intoxication
Method	Breath alcohol concentration to BAC	Breath alcohol concentration to BAC
Measurement Range	0.00% to 0.40%	0.00% to 0.40%
Measurement Accuracy	+/-0.01 at 0.10% BAC	+/-0.01 at 0.10% BAC
Sensor Type	Semiconductor oxide sensor	Semiconductor oxide sensor
Power Source	9V alkaline battery	Two 1.5V AA batteries
Testing Capacity	Approx. 300 (1 battery)	Approx. 300 (2 batteries)
Certification	DOT / NHTSA	DOT / NHTSA
Practitioner Use	Over-the-counter	Over-the-counter
Construction	Circuit board housed in plastic casing, replaceable mouthpieces	Circuit board housed in plastic casing, replaceable mouthpieces
Warmup Time	About 20 seconds	About 20 seconds
Display	3-digit LED	3-digit LED
Dimensions	5" x 3¼" x 1"	5½" x 3" x 2"
Weight	171 g	117 g

6. Conclusion

Benchmark and safety testing, EMC/DOT testing and risk analysis, as well as practical user testing, reveal that the AL-6000 performs within the same ranges of safety and effectiveness as those of the predicate device. The AL-6000 and predicate device describe the same indications for use and similarly well-proven methods of technical analysis (breath alcohol to BAC using semiconductor oxide sensors). Results show that the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Sentech Korea Corp.
c/o Mr. Matthew H. Son
President
AK Solutions USA LLC
21 Grand Ave. Suite 103
Palisades Park, NJ 07650

MAY 11 2006

Re: k060343
Trade/Device Name: AL-6000 Alcohol Breath Tester
Regulation Number: 21 CFR§862.3050
Regulation Name: Breath-alcohol test system
Regulatory Class: Class I
Product Code: DJZ
Dated: February 10, 2006
Received: March 1, 2006

Dear Mr. Son:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060343

Device Name: AL-6000 Alcohol Breath Tester

Indications For Use:

The AL-6000 Breath Alcohol Tester is a screening device for the rapid detection of alcohol in the human breath. Measurements obtained by this device are used in the diagnosis of alcoholic intoxication.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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